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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,965	01/12/2001	Matthew Thomas Heisey	8398	1681

27752 7590 07/30/2002

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,965	Applicant(s) Heisey et al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

☒ Responsive to communication(s) filed on **-02/01/02 (IDS) & 05/08/02 (amdt B)-**.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merit is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claims **--1-2, 4, 7-14, 16 and 19-50--** are pending in the application. Claims **-3, 5-6, 15 & 17-18-** have been cancelled.

Of the above claim(s) **--[]--** is/are withdrawn from consideration.

☐ Claim(s) **--[]--** is/are allowed.

☒ Claims **--1-2, 4, 7-14, 16 and 19-50--** are rejected.

☐ Claim(s) **--[]--** is/are objected to.

☐ Claim(s) **--[]--** are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on **-[]-** are ☐ approved ☐ disapproved.

☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) **-[]-**.

☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: **-[]-**.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **-[]-**

☒ Notice of Reference(s) Cited, PTO-892 (Update)

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other: **-[]-**

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/759,965

Part of Paper No. **11**

Copy for ☒ FILE ☐ APPLICANT

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Claims 3, 5-6, 15 and 17-18 have been cancelled, claims 1, 4, 13, 16, 19 and 36 have been amended, and no new claims have been added as per the amendment filed May 8, 2002. An Information Disclosure Statement (IDS) filed February 1, 2002 has been received with all cited references and made of record.

Claims 1-2, 4, 7-14, 16 and 19-50 remain in the case.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims 43-46 are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. ,1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

Applicant is referred to the term "use" at line 3 of each of claims 43-46. Examiner suggests replacement of the noted term with either the term -- administration -- or the term -- ingestion -- to overcome the instant grounds of rejection.

Claims 1-2, 4, 7-14, 22-36 and 43-46 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1, 13, 22 and 34 the terms "gelatin," "cartilage," "amino sugars," and "glycosaminoglycans" are directed to a vast array of compounds only a few of which are known to have the desired beneficial effects claims. The remainder of the specific compounds included within the generic terms noted are not properly enabled by the instant written description and are therefore not properly enabled.

Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

Applicant's claims are -- pharmaceutical composition -- claims and are therefore subject to the standards which also apply to medicinal methods of treating claims of the kind also found in this application. While the use of generic terminology in non-medicinal patent claims is a common practice, it is not a common practice in this area. Applicant is again respectfully requested to limit the claimed subject matter to reasonably correspond to the scope enabled by the examples; i.e. replace the generic terms with the chemical names of compounds either known in the art or demonstrated by applicant's data to be active ingredients.

Claims 1, 13, 22 and 34 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 13, 22 and 34 the term "precursors" is indefinite for failure to specify which particular compounds are being claimed as active ingredients.

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Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

Applicant argues that the noted term "are definite when read by one of ordinary skill in the art in light of the specification." Examiner respectfully disagrees. Examiner notes that the ordinary practitioner has not been provided adequate guidance as to which particular chemical compounds are included within the scope of the noted "precursors" and which are not. For example, the compound "methylsulfonylmethane," aka -- $\text{CH}_3\text{-SO}_2\text{-CH}_3$ --, may be synthesized from sulfur, carbon, hydrogen and oxygen, or from $\text{CH}_3\text{-Cl}$, H_2S , and an oxidizing agent, etc., etc. Which if any of the noted elements or compounds/reagents is intended to be included within the scope of the noted claims as "precursors" to the named compound?" Suggestions that the chemical compounds are defined within the instant disclosure or a patent incorporated by reference is not deemed to be an adequate response because at page 10, first sentence of the last paragraph, the term "[n]on-limiting examples of precursors of methylsulfonylmethane include methionine and methyl sulfide" fails to provide well defined metes and bounds and therefore does not overcome the instant grounds of rejection. Examiner notes that the term "includes" is synonymous with the term -- comprises --, a term which is judicially recognized to imply the broadest possible scope, and therefore by defining the scope of "precursors" provided in the disclosure so broadly, said term effectively prevents applicant from overcoming the instant question of metes and bound. Appropriate clarification is respectfully requested.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the

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statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims 1-2, 4, 7-14, 16 and 19-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 09/760,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment and the alleged active ingredients of the claimed compositions are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

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Applicant has acknowledged the instant grounds of rejection and indicated that a terminal disclaimer would be filed if the rejection was repeated. .

5 Claims 1-2, 4, 7-14, 16 and 19-50 are rejected under the
judicially created doctrine of obviousness-type double patenting as being
unpatentable over claims 1-23 of copending Application No.
09/586,520. Although the conflicting claims are not identical, they are
not patentably distinct from each other because the methods of
10 treatment and the alleged active ingredients of the claimed compositions
are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection
because the conflicting claims have not in fact been patented.

Applicant's arguments filed May 8, 2002 have been fully considered
but they are not persuasive.

15 Applicant is referred to the response following the first double
patenting rejection.

20 Claims 1-2, 4, 7-14, 16 and 19-50 are rejected under the
judicially created doctrine of obviousness-type double patenting as being
unpatentable over claims 1-19 of copending Application No.
09/586,284. Although the conflicting claims are not identical, they are
not patentably distinct from each other because the methods of
treatment and the alleged active ingredients of the claimed compositions
are directed to substantially overlapping subject matter.

25 This is a provisional obviousness-type double patenting rejection
because the conflicting claims have not in fact been patented.

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Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

Applicant is referred to the response following the first double patenting rejection.

5 Claims 1-2, 4, 7-14, 16 and 19-50 are rejected under the
judicially created doctrine of obviousness-type double patenting as being
unpatentable over claims 1-32 of copending Application No.
09/586,514. Although the conflicting claims are not identical, they are
not patentably distinct from each other because the methods of
10 treatment and the alleged active ingredients of the claimed compositions
are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection
because the conflicting claims have not in fact been patented.

15 Applicant's arguments filed May 8, 2002 have been fully considered
but they are not persuasive.

Applicant is referred to the response following the first double
patenting rejection.

20 Claims 1-2, 4, 7-14, 16 and 19-50 of this application conflict
with claims of four other patent applications noted supra. 37 C.F.R.
§1.78(b) provides that when two or more applications filed by the same
applicant contain conflicting claims, elimination of such claims from all
but one application may be required in the absence of good and
sufficient reason for their retention during pendency in more than one
application. Applicant is required to either cancel the conflicting claims

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from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 "A patent may not be obtained though the invention is not identically disclosed or
described as set forth in section 102 of this title, if the differences between the
subject matter sought to be patented and the prior art are such that the subject
matter as a whole would have been obvious at the time the invention was made to a
10 person having ordinary skill in the art to which said subject matter pertains.
Patentability shall not be negated by the manner in which the invention was made."

Claims 1-2, 4, 7-14, 16 and 19-50 are rejected under 35 U.S.C.
§103(a) as being unpatentable over any one of PTO-1449 references AB,
AC, AE, AK, AN, AP, AU, AW, AZ, BA, BD, BE, BF, BG, BL, CA and
CB and PTO-892 references A, R, S and T wherein the ingredients listed
15 as active are repeatedly disclosed as being known in the art as
appropriate constituents of joint assisting food composition.

In light of applicant's failure to provide any data to support an
unexpected benefit from the instant claimed compositions, the instant
claimed compositions, kits thereof and methods of administration
20 thereof, are deemed to lack patentable distinction as being nothing more
than a mixture of substances known in the prior art and therefore
obvious compositions to be administered to a host in need thereof. Any
compounds (e.g. sweeteners) not specifically found in the instant cited
references are certainly known in the prior art and may be found in
25 standard texts on pharmacology and/or food additives.

Therefore, the instant claimed compositions, kits and methods of
administration would have been obvious to one of ordinary skill in the
art having the above cited reference before him at the time the invention
was made.

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Applicant's arguments filed May 8, 2002 have been fully considered but they are not persuasive.

Applicant is respectfully requested to note that edible pharmaceutical compositions including as active ingredients
5 glucosamine, acetyl glucosamine, mixtures thereof and mixtures of salts thereof, and optionally together with chondroitin are on sale widely; e.g. on the vitamin shelf at Walmart. A careful and complete reading of the voluminous instant cited prior art will reveal repeatedly that supplementation of the mammalian diet with glucosamine and/or
10 chondroitin is notoriously well known in the art to be "chondroprotective;" i.e. effective in the treatment of joint and connective tissue disorders, including arthritis in >80% of a substantial human test population (See PTO-892 ref. R). Even a cursory scanning of the titles and abstracts of the cited references will produce the same
15 result. As to supplemental additives such as "edible acids," vitamins, minerals, omega-3-fatty acids, hyaluronic acids, etc., applicant has listed same but has not provided any clearly convincing showing that the addition of these materials to a glucosamine and/or chondroitin containing pharmaceutical composition leads to any unexpected
20 medicinal benefit. Therefore, the instant grounds of rejection are deemed to remain valid and for this reason have been maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL
25 ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY

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ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH
SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY
PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND
ANY EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE
5 CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO
EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN
SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600
via facsimile transmission(FAX). The transmission of such papers must
10 conform with the notice published in the Official Gazette (1096 OG 30,
November 15, 1989). The telephone numbers for the FAX machines
operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Examiner L. E.
15 Crane whose telephone number is 703-308-4639. The examiner can
normally be reached between 9:30 AM and 5:00 PM, Monday through
Friday.

If attempts to reach the examiner by telephone are unsuccessful, the
examiner's supervisor, Mr. Johann Richter, can be reached at (703)-308-
20 4532.

Any inquiry of a general nature or relating to the status of this
application should be directed to the Group 1600 receptionist whose
telephone number is 703-308-1235.

Serial No. 09/759,965

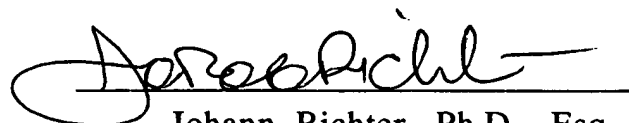
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Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600